



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 15, 2002

MEMORANDUM

Subject: Efficacy Review for Agri-phene Low pH Germicidal Detergent, EPA Reg. No. 211-62-10504.
DP Barcode: D

From: Michele E. Wingfield, Chief
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Thru: Michael Hardy, Coordinator
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To: Dr. Brenda Mosley
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Producer: Central Solutions
POB 15276
3130 Brinkerhoff Road
Kansas City, Kansas 66115

Formulation From Label:

Active Ingredient(s)

% by

	<u>wt</u>
ortho-phenylphenol	8.085
ortho-benzyl-para-chlorophenol	6.650

I. BACKGROUND

The submitted studies, received December 14, 2001, were conducted at the Consumer Analytical Laboratory, Ohio Department of Agriculture, as part of the Antimicrobial Testing Program. On July 6, 2000, the laboratory received one sample of the product. Sample number 062000F257401-F (lot no. 02170022), was tested using the AOAC Use-Dilution Test against *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

II. USE DIRECTIONS

For broad spectrum disinfection of gram negative (as demonstrated by efficacy against *Salmonella choleraesuis*) and gram positive (as demonstrated by efficacy against *Staphylococcus aureus* and *Pseudomonas aeruginosa*) bacteria, add ½ ounce Low pH phenolic 256 per 1 gallon of water. Remove heavy soil or gross filth then apply solution with a mop, cloth, sponge, or hand-pump trigger sprayer so as to wet surface thoroughly. Allow to remain wet for 10 minutes and then air dry. If higher detergency is desired, increase dilution to 1 ounce per gallon of water.

III. AGENCY STANDARD FOR DISINFECTANTS HOSPITAL OR MEDICAL ENVIRONMENT

Test requirements. When a product is recommended in labeling for use in hospitals, clinics, dental offices, nursing homes, sickrooms, or any other medical-related facility, the following requirements apply: Sixty carriers for each of three samples, representing three different batches, one of which is at least 60 days old, must be tested against each of the following: *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442).

Performance standard. The product must kill the test microorganisms on 59 out of each set of 60 carriers/slides to provide significance at the 95 percent confidence level.

IV. BRIEF DESCRIPTION OF THE DATA

Testing of the three samples of the product was conducted on August 1, 2001 against *Staphylococcus aureus*, and on May 22, 2001 against *Pseudomonas aeruginosa*. The method used was the AOAC Use-Dilution Test with the following modifications: The product was diluted 1:256 in 400 ppm (CaCO₃) hard water. 5% fetal bovine serum was added to the inoculum as a soil load. The carrier count was 7.5 x 10⁶ CFU/carrier for *S. aureus* and 6.3 x 10⁶ CFU/carrier for *P. aeruginosa*. Testing was conducted at a contact time of 10 minutes at room temperature. Lethen broth was used as the neutralizer and subculture medium. The treated carriers were

incubated for 48±2 hours at 37°C.

V. RESULTS

Sample Number	Lot Number	Organism	Number +/- Number Tested
062000F257401-F	02170022	<i>Staphylococcus aureus</i>	3/60
		<i>Pseudomonas aeruginosa</i>	1/60

VI. CONCLUSIONS

The submitted data does not support the effectiveness of the product, Agri-phene Low pH Germicidal Detergent (EPA Reg. No. 211-62-10504) as a broad spectrum disinfectant when tested against *Staphylococcus aureus* (ATCC 6538) by the AOAC use-Dilution Test for a 10 minute contact time at room temperature.

VII. RECOMMENDATIONS

The company should be notified of the one batch failure and arrangements made for removal of the batch from the marketplace. In addition, two additional batches of the product should be tested in order to complete post-registration testing of this product.